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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/920, 453 09/12/97 BALES

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EXAMINER

QM41/1217

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ELI REED, G

ART UNIT PAPER NUMBER

3736

DATE MAILED:

12/17/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/928,453</b>	Applicant(s) <b>Bales et al.</b>
	Examiner <b>Samuel Gilbert</b>	Group Art Unit <b>3736</b>

Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 22-63 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 22-63 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3736

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 1/7/98 has been considered.

### ***Drawings***

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Claim Rejections - 35 USC § 112***

3. Claims 26, 32, and 46-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 46 -claims set forth an end effector assembly wherein the assembly comprises a first and second jaws. Further, the first jaw is "pivotally disposed" the claims lacks the structure necessary to provide the support for a pivotally disposed jaw. No structure is set forth to pivot from.

Claims 26, 32, 50, and 56 - these claims set forth "teeth radially disposed on the edge surfaces" it is unclear how the teeth are radially disposed on the edge. Is the edge surface radial?

Art Unit: 3736

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 22, 23, 25-34, and 43, 46, 47, and 49-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Nierman (4,880,015).

Claims 22, 23, 46 and 47 - Nierman teaches a biopsy device shown generally in figure 5. Jaw cups -46- are pivotally disposed. The examiner is taking elements -43-, -44- and -64- as the actuator. The flexible shaft -45- is hollow.

Claims 25-34 and 49-58 - Figure 6 shows the jaws -46- having triangular teeth around the radius of the jaw cups. The teeth shown on the jaw cups are displaced by one half pitch, shown by the top jaw starting with a one half tooth having two full teeth and then ending with another one half tooth. The bottom jaw having three full teeth. These teeth will mate.

Claim 43 - shaft -45- is formed by a coiled spring like cable. Applicant's attention is invited to column 7 line 60.

Art Unit: 3736

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 24, 36-42, 48, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nierman in view of Salerno (4,953,559).

Claims 24 and 48 - Nierman teaches a device as claimed but does not set forth a clevis pin used to pivot jaws -46-. It is set forth that the jaws -46- are formed cross and end in hinges -59-. It is well known in the art to use a clevis pin at the point in which jaw pieces cross to insure consistent movement of the jaws. An example of a clevis pin is set forth in Salerno as element -11- and unnumbered but shown in figure 4. It is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a clevis pin at the point where the jaws cross in order to provide consistent movement of the jaws.

Claims 36-40 - Nierman sets forth jaws that end with hinges -59-, the examiner is taking the hinges to be tangs. Nierman further discloses attaching wire -47- to the hinges but the manner in which the connection is made is not set forth. Nierman does teach two methods of attaching wire -48- to element -57-, either by block -56- or as shown in figure 8A the wire is placed in a bore and then welded in place. In column 10 line 19, Nierman indicates other similar means

Art Unit: 3736

could be used to connect the wire. It is the examiner position that the means used to connect wire -48- to element -57- would be the same as that used to connect wire -47- to the hinges -59-.

Figure 8A of Nierman shows the welded configuration. It is the examiner's position that the wire -48- is placed in a bore because the wire is within element -57- as shown by the dashed lines but the end of the wire and weld is shown on the outside of element -57- as shown by solid lines.

Salerno further illustrates a tang having a bore and a pull wire attached, applicant's attention is directed to bore -17- and the pull wire shown at -15- and -16-, in figure 2. From the above it would have been obvious design expedient to one of ordinary skill in the art to connect the pull wire -47- to hinges -59- by placing the wire in a bore and welding the wire in place. If the wire is welded in place as taught by Nierman it would not be necessary to form a loop in the pull wire. Nierman teaches only one pull wire -47- connecting to both hinges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use two pull wires, one connected to each jaw as a duplication of elements.

Claims 41 and 42 - wire -47- is attached to grip -43-. The examiner is taking element -43- to be a spool.

8. Claims 35, 44, 45, 59, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nierman in view of Macek et al. (4,763,668).

Nierman teaches a device as claimed but does not teach elongated hemispherical shaped jaws or a sharpened needle between the jaws. Macek et al teaches a biopsy device having a pair

Art Unit: 3736

of hemispherically shaped jaws and a needle between the jaws. The use of a needle in a biopsy device is well known in the art as shown by Macek et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a sharpened needle with the device of Nierman as is shown by Macek et al to provide a needle to hold the sample to be cut to provide a more accurate cut.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of the jaw of Nierman to be hemispherical as shown by Macek et al as an ordinary design expedient.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 22-63 are rejected under the judicially created doctrine of double patenting over claims 1-3 of U. S. Patent No. 5,133,727 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Art Unit: 3736

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a biopsy device having jaws and teeth on the jaws.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

11. Claims 22-63 are rejected under the judicially created doctrine of double patenting over claims 1-21 of U. S. Patent No. 5,507,296 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a biopsy device having jaws with cutting teeth.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Art Unit: 3736

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patents 4,427,014 and 2,994,321 teach related biopsy devices.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Gilbert whose telephone number is (703) 308-3553. The examiner can normally be reached on Monday through Friday from 9:00 A.M. to 4:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858. The Group facsimile number is (703) 305-3590.

Samuel Gilbert



Primary Examiner  
December 13, 1998  
Art Unit 3736